UNITED STATES PATENT AND TRADEMARK OFFICE

SERIAL NO: 76/470648

APPLICANT: Genitope Corporation

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BEFORE THE TRADEMARK TRIAL AND APPEAL BOARD ON APPEAL

MARK:

CORRESPONDENT'S REFERENCE/DOCKET NO: GENITOPE-075

CORRESPONDENT EMAIL ADDRESS:

Please provide in all correspondence:

1. Filing date, serial number, mark and applicant's name.
2. Date of this Office Action.
3. Examining Attorney's name and Law Office number.
4. Your telephone number and e-mail address.

EXAMINING ATTORNEY'S APPEAL BRIEF

Applicant has appealed the Trademark Examining Attorney's Final Refusal to register the trademark, a design of a man with a fingerprint design superimposed ("fingerprint man design"), for "biopharmaceutical preparations used to treat cancer in humans, namely, individualized cancer treatments prepared specifically for each individual patient from whom tumor tissue has been received" on the grounds that the specimens are unacceptable as evidence of trademark use. Section 1(a)(1)(C) of the Trademark Act, 15 U.S.C. § 1051(a)(1)(C); 37 C.F.R. Section 2.56.

I. FACTS

Applicant applied for registration on the Principal Register of the trademark fingerprint man design for "biopharmaceutical preparations used to treat cancer in humans, namely, individualized cancer treatments prepared specifically for each individual patient from whom tumor tissue has been received" on November 29, 2002. Applicant filed a Statement of Use on February 17, 2004. The

original specimen was merely the fingerprint man design next to the wording "MyVax Personalized Immunotherapy." On March 11, 2004, the Examining Attorney rejected this specimen as being merely an electronic version of the design, not a specimen showing use of the mark on the goods in commerce. On September 3, 2004, the applicant submitted a substitute specimen consisting of a web page with the same image as originally submitted, but in the context of a "Product Overview." On November 22, 2004, the Examining Attorney finally refused the specimens. Registration was refused under Section 1 (a)(1)(C) of the Trademark Act, 15 U.S.C. § 1051(a)(1)(C), and 37 C.F.R. Section 2.56, because the specimens fail to show use of the mark on or in association with the goods. This appeal, filed on July 22, 2005, follows the Examining Attorney's Final Refusal[1] on this issue dated November 22, 2004.

II. ARGUMENT

THE SPECIMENS FAIL TO SHOW USE OF THE MARK ON THE GOODS IDENTIFIED IN THE APPLICATION, AS REQUIRED UNDER SECTION 1(a)(1)(C) OF THE TRADEMARK ACT, 15 U.S.C. § 1051(a)(1)(C) and 37 C.F.R. SECTION 2.56.

Under 37 C.F.R. Section 2.56, "[t]he specimens shall be duplicates of the labels, tags, or containers bearing the trademark, or the displays associated with the goods and bearing the trademark (or if the nature of the goods makes use of such specimens impracticable then on documents associated with the goods or their sale)." Examples of acceptable specimens are varied and can include labels, tags, materials associated with the goods at the point of sale and screen displays. *See* TMEP section 905.04. However, advertising materials are not normally acceptable.

TMEP section 905.05 states that,

> Advertising material is generally not acceptable as specimens for goods. Any material whose function is merely to tell the prospective purchaser about the goods, or to promote the sale of the goods, is unacceptable to support trademark use. Similarly, information or instruction sheets are generally not acceptable for showing trademark use. *In re ITT Rayonier Inc.*, 208 USPQ 86 (TTAB 1980); *In re Bright of America*, Inc., 205 USPQ 63 (TTAB 1979). *But see In re Ultraflight Inc.*, 221 USPQ 903 (TTAB 1984).
>
> The following types of items are generally considered to be merely advertising and, therefore, unless they comprise point-of-sale material, are not acceptable as specimens of use on goods: advertising circulars and brochures, price lists, announcements, publicity releases, listings in trade directories, and business cards. Moreover, material which is used

by the applicant in conducting its internal business is unacceptable as specimens of use on goods. These materials include all the papers whose sole function is to carry out the applicant's business dealings, such as invoices, bill heads, waybills and business stationery. *See In re Chicago Rawhide Mfg. Co.*, 455 F.2d 563, 173 USPQ 8 (CCPA 1972); *In re Bright, supra; Varian Associates v. IMAC Corp.*, 160 USPQ 283 (N.D. Ill. 1968); *Upco Co. v. Speed Crete of La., Inc.*, 154 USPQ 555 (TTAB 1967); *Dynacolor Corp. v. Beckman & Whitley, Inc.*, 134 USPQ 410 (TTAB 1962); *Pendleton Woolen Mills v. Eloesser-Heynemann Co.*, 133 USPQ 211 (TTAB 1962); *Boss Co. v. Homemaker Rugs, Inc.*, 117 USPQ 255 (N.D. Ill. 1958).

In this case, the applicant has submitted two specimens to support its use of the mark, fingerprint man design, for "biopharmaceutical preparations used to treat cancer in humans, namely, individualized cancer treatments prepared specifically for each individual patient from whom tumor tissue has been received." The first specimen submitted was merely an electronic image of the fingerprint man design with the wording "MyVax Immunotherapy" to the right of the image. The substitute specimen submitted consists of a single page from applicant's website entitled "MyVax Personalized Immunotherapy." The fingerprint man design is located to the left of the MyVax title above the text on the page relating to the "Product Overview." In this case, the specimens submitted are merely advertising for the goods that will be used in the clinical trials discussed on the webpage.

Applicant asserts that the specimen "clearly qualifies as a display associated with the goods," and cites the Board's decision in *In re Dell, Inc,* 71 U.S.PQ.2d 1725 (TTAB 2004) for the proposition that a website can qualify as a display associated with the goods as long as the mark appears on the web page in a manner that associates the mark with the goods. However, the Board also required in *Dell* that a website which displays the product in a manner which associates the mark with the goods, must also provide a means for ordering the goods. In this case, there is no ability for any consumer, whether it be a patient or physician, to order applicant's goods, biopharmaceutical preparations, from applicant's website. Such ability is not reflected in the specimen of record. In fact, the specimen indicates in the top right corner that no one would be able to order applicant's product as the "study [is] closed to patient registration." Further, the specimen reflects that any consumer, be it a patient or doctor, may only request further information as noted in the last sentence of the page referring consumers to the links, "Patient Backgrounder" or "Patient Resources," not links such as "Buy Online," "Customize it," or "Add to Cart."

TMEP Section 905.04 allows applicants "to submit documents associated with the goods or their

sale as specimens where the goods are such that placement of the mark on the goods, containers, tags, labels or displays associated with the goods is impracticable." However, "[a] mere assertion of impracticability may not suffice to establish that such use is impracticable; rather, the record must indicate that the goods are in fact of such a nature." Although applicant argues that the goods are "not amenable to the type of point-of-sale displays that allow direct ordering of the goods by the general public," applicant does not argue that the placement of the mark on the goods themselves, their containers, tags or labels would be impracticable. To correct the inadequate specimens, all that needed to be submitted were copies of labels or tags from the bottles, I-V bags or packaging that the goods themselves would be delivered to the doctors in. As applicant admits the goods are "highly-specialized, custom-manufactured pharmaceutical preparations based on tissue samples from individual patients," it is certain that the goods themselves must utilize some type of label or method of identification affixed to the goods if only to identify these specific patients for whom the goods are made. The applicant never raised the possibility that "routine" or "ordinary" specimens were impracticable but has merely argued that the specimens submitted are acceptable as a display associated with the goods.

Finally, the specimens do not provide all of the information necessary to order the goods but merely include an address and phone number, as any normal advertising may. The court in *Land's End* held that the catalogs in question were acceptable because "[a] customer can identify a listing and make a decision to purchase by filling out the sales form and sending it in or by calling in a purchase by phone." *Land's End*, 24 USPQ2d at 1316. The specimens submitted by the applicant do not include a sales form, a price for the goods, or any of the other information normally associated with ordering goods via phone or mail. A phone number, an internet address and a mailing address are included but no offers to accept orders or special instructions on placing orders appear anywhere on the specimens.

Clearly, in viewing the use of the mark fingerprint man design on the specimens of record, the primary significance to the purchasing public would be that of advertising, promotional and/or informational materials. The applicant has failed to submit adequate material evidence to rebut this. Therefore, the specimens fail to show use of the mark on acceptable specimens for the goods.

III. CONCLUSION

For the foregoing reasons, the refusal to registration under Trademark Act Section 1(a)(1)(C) and 37 C.F.R. Section 2.56 should be affirmed.

Respectfully submitted,

/Jill I. Prater/
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[1] This application was originally assigned to Examining Attorney John S. Yard.

Genitope Corporation

Delivering on the promise of personalized medicine™

Phase 3 Clinical Trial Update:
Study Closed to Patient Registration

Click here for more information

Patient Resources

Genitope Corporation is committed to helping patients who are diagnosed with non-Hodgkin's lymphoma (NHL). First and foremost, our company is focused on developing a personalized immunotherapy product for patients with NHL. Genitope's lead product candidate, MyVax® Personalized Immunotherapy (previously known as GTOP-99), is currently being tested in a pivotal Phase 3 trial in patients with previously untreated, stage III-IV follicular NHL. The patient registration phase of the study has been completed. Phase 2 studies in patients with B-cell NHL are either ongoing or have been completed. Through our website, Genitope Corporation strives to provide patients with the information necessary to make an educated and informed decision regarding their treatment options.

Below are several areas that patients may find especially useful (click on the underlined words to link to the specific sections):

- The Clinical Trials section provides information about Genitope's ongoing and closed clinical studies. Here, you will find:
  - A summary of the ongoing pivotal Phase 3 trial for patients with previously untreated, stage III-IV follicular non-Hodgkin's lymphoma. The patient registration phase of the study has been completed.
  - A summary of Genitope's ongoing rollover trial for patients who enter our Phase 3 trial but who fail to achieve at least a partial response after eight cycles of CVP chemotherapy or who progress during the mandatory rest

cycles of CVP chemotherapy or who progress during the mandatory rest period. This trial explores the use of our patient-specific product in conjunction with the anti-CD20 antibody, Rituxan® (Rituximab). All patients enrolled in this study will receive Rituxan® followed by our experimental product, MyVax® Personalized Immunotherapy.

- Brief summaries of closed Phase 2 clinical trials that are in long term follow-up.

- A contact form to use if you have any questions or are interested in receiving further information about our clinical trials.

- The Product Overview section describes our lead therapeutic product, MyVax® Personalized Immunotherapy, and how we make it.

- This Patient Resources area provides educational resources for lymphoma patients and their caregivers. Here, you will find:

  - Frequently Asked Questions - a list of frequently asked questions and answers about Genitope's lead therapeutic product, MyVax® Personalized Immunotherapy

  - Other Resources - a list of organizations providing information and services relevant to the lymphoma community

  - Calendar of Events - a list of nationwide educational programs and conferences for lymphoma patients in which Genitope has participated or plans to participate

  - Glossary of Terms - definition of terms found throughout this website

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Genitope Corporation

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New Educational Webcasts

Listen to what the experts say about personalized immunotherapy for NHL

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Request Information

If you would like more information about Genitope Corporation, MyVax® Personalized Immunotherapy (previously known as GTOP-99), or about Genitope's clinical trials, please complete and submit the form below, or call our toll-free hotline at 1-866-GENITOP (1-866-436-4867).

A Genitope representative will respond to your information request as soon as possible. We strive to respond to all inquiries within one week of receipt.

Request Information Form:

Title: Mr.

First Name:

Last Name:

Telephone:

E-mail Address:

Address:

City:

State:

Zip Code:

I prefer to be contacted by: Telephone

Please tell us how you found out about Genitope and its clinical trial(s):

- ☐ Clinical Trials Fair
- ☐ Newspaper Article
- ☐ Television News Report

(check all that apply)

- [ ] Television News Report
- [ ] Internet Search Engine
- [ ] Magazine Advertisement
- [ ] Friend or Relative
- [ ] Internet Chat Room
- [ ] Physician
- [ ] Nurse

- [ ] Other (please specify below)

- [x] Please send me the Patient Backgrounder: Personalized Vaccine Therapy for Non-Hodgkin's Lymphoma. *Please note that this publication will arrive within 3 weeks.

- [ ] I have a specific question:

Genitope respects your privacy and will keep your personal information confidential. For more information on our privacy policy, please click here. By submitting this form, you acknowledge that you are voluntarily providing your information to Genitope.

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Phase 3 Clinical Trial Update:
Study Closed to Patient Registration
Please click here for more information

Frequently Asked Questions

The following Frequently Asked Questions and answers provide patients with information about Genitope's lead product candidate, MyVax® Personalized Immunotherapy. Click on an area of interest, or click on a specific question to read its answer.

Click here to view the FAQs online with Adobe Acrobat Reader, which can be easily downloaded at no cost and instructions are provided.

About MyVax® Personalized Immunotherapy

- What is MyVax® Personalized Immunotherapy?
- Are there other names for personalized immunotherapy?
- What is MyVax® Personalized Immunotherapy made of?
- How does MyVax® Personalized Immunotherapy work?
- What is the difference between MyVax® Personalized Immunotherapy and vaccines given to prevent diseases such as measles, mumps, or polio?
- Since it is made from the patient's tumor, can MyVax® Personalized Immunotherapy cause the patient's lymphoma to come back?
- For what diseases is Genitope testing MyVax® Personalized Immunotherapy?

Making MyVax® Personalized Immunotherapy

- What is needed from the patient to make MyVax® Personalized Immunotherapy?
- How is MyVax® Personalized Immunotherapy made?
- How does Genitope make sure patients get their own specific personalized immunotherapy?
- Can MyVax® Personalized Immunotherapy be made for every patient?

What to Expect When Receiving MyVax® Personalized Immunotherapy

- Why is it recommended that patients have chemotherapy before receiving MyVax® Personalized Immunotherapy?
- How is MyVax® Personalized Immunotherapy given?
- What side effects do patients experience with MyVax® Personalized Immunotherapy?
- What can be done to manage these side effects?

Talking to Your Healthcare Team About MyVax® Personalized Immunotherapy

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About MyVax® Personalized Immunotherapy

What is MyVax® Personalized Immunotherapy?

MyVax® Personalized Immunotherapy ("MyVax®") is the proposed brand name for an exciting potential treatment currently being studied in clinical trials for patients with B-cell non-Hodgkin's lymphoma (NHL). It is a type of treatment that uses a person's immune system (thus, the term *immunotherapy*) in an attempt to combat disease. MyVax® is called personalized immunotherapy because it is developed from a protein called an idiotype protein, or Id, which is identified from the patient's tumor cells and is unique to that patient's tumor. In fact, the Id can be thought of as a tumor "fingerprint." MyVax® is different from currently available therapies in that it is made individually and specifically for each patient. Because it has been custom-designed to work with each patient's specific immune system and to target each patient's particular tumor, healthy cells within the patient's body should not be affected.

Are there other names for personalized immunotherapy?

Yes, you may also hear personalized immunotherapy referred to as active idiotype immunotherapy, idiotype (Id) vaccines, or therapeutic idiotype vaccines. These are simply different names for the same therapeutic approach.

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What is MyVax® Personalized Immunotherapy made of?

MyVax® Personalized Immunotherapy is composed of (1) the patient- and tumor-specific idiotype (Id) protein, and (2) a second protein called keyhole limpet hemocyanin (KLH). KLH comes from a giant sea snail that lives off the coast of California. It is highly immunogenic, meaning that when it is put into the body, the immune system responds strongly to it—and to anything attached to it.

Although technically not part of the vaccine, an adjuvant, or substance that enhances the immune response, is administered with MyVax®. This adjuvant is called granulocyte macrophage-colony stimulating factor (GM-CSF).

How does MyVax® Personalized Immunotherapy work?

The immune system is the body's natural defense mechanism. It is designed to prevent and combat disease. It works by distinguishing between the body's own cells and those of foreign invaders, such as viruses or bacteria. While the immune system is good at defending the body against infectious disease, it is generally ineffective in defending the body against cancer, because cancer arises from the body's own cells. Because of this, the immune system thinks the cancerous cells are part of the body, and thus, they are not attacked.

MyVax® Personalized Immunotherapy is designed to help the patient's immune system to recognize

MyVax® Personalized Immunotherapy is designed to help the patient's immune system to recognize his or her tumor as foreign (i.e., something that should be attacked). When the patient- and tumor-specific idiotype (Id) is joined to KLH and the Id-KLH immunotherapy is then introduced into the body, a strong immune response is typically generated against KLH and—because the Id protein is attached—theoretically against the Id protein. This immune response not only targets the Id proteins attached to KLH, but also the Id proteins on the tumor cells from which the sample used to make MyVax® was originally taken. The treatment is tumor-specific, so that the patient's immune system should target only the cancer cells for destruction, while leaving normal cells unharmed.

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What is the difference between MyVax® Personalized Immunotherapy and vaccines given to prevent diseases such as measles, mumps, or polio?

Therapeutic idiotype (Id) vaccines such as MyVax® Personalized Immunotherapy are used to treat diseases (i.e., cancer) that are already present in the body, in an effort to prevent them from coming back or to keep them from getting worse. Vaccines for measles, mumps, polio, and other diseases, on the other hand, are prophylactic, or preventative, vaccines used to prevent disease from occurring in the first place. Another difference between the two vaccines is that MyVax® is made individually for each patient, while preventative vaccines are mass-produced.

Since it is made from the patient's tumor, can MyVax® Personalized Immunotherapy cause the patient's lymphoma to come back?

MyVax® Personalized Immunotherapy contains a recombinant, or genetically engineered, form of the idiotype (Id) protein, not live tumor cells. Therefore, it cannot cause a recurrence of lymphoma. Disease recurrence is thought to be due to residual circulating lymphoma cells (i.e., cells not destroyed by previous therapies) and/or genetic mutations related to the disease.

For what diseases is Genitope testing MyVax® Personalized Immunotherapy?

MyVax® Personalized Immunotherapy is currently being tested only in patients with B-cell NHL. Specifically, a phase 3 study in patients with follicular NHL in first remission following chemotherapy is ongoing. Similar personalized immunotherapies may soon be tested in patients with other B-cell or T-cell malignancies.

Making MyVax® Personalized Immunotherapy

What is needed from the patient to make MyVax® Personalized Immunotherapy?

Since MyVax® Personalized Immunotherapy is made specifically for each individual patient to combat that patient's tumor, a sample, or biopsy, from the tumor is needed. Excisional lymph node biopsies are best, but it is possible to work with material obtained from a core needle biopsy, fine needle aspiration, or bone marrow or peripheral blood sample. The cells do not need to be live, so it is OK if the samples are frozen. Note that cells that are preserved, or "fixed," cannot be used.

Tissue obtained during the diagnostic biopsy can often be saved and utilized to make a personalized immunotherapy. In some instances, a second biopsy may be needed to obtain enough tumor cells that

are expressing the idiotype (Id) protein.

How is MyVax® Personalized Immunotherapy made?

Once Genitope has a biopsy sample from the tumor, the next step is to identify and isolate the genetic material associated with the specific idiotype (Id) that that specific tumor is expressing, or producing. This genetic material is then used to produce a recombinant, or genetically engineered, version of the Id protein, which is then purified and combined with KLH. (See Question: What is MyVax® Personalized Immunotherapy made of?)

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How does Genitope make sure patients get their own specific personalized immunotherapy?

At multiple points during the production process, the idiotype (Id) contained in the patient's immunotherapy is compared to the Id from the biopsy specimen. This ensures that they match and that the patient is getting a personalized immunotherapy that specifically targets his/her tumor.

Can MyVax® Personalized Immunotherapy be made for every patient?

Currently, MyVax® Personalized Immunotherapy is an investigational therapy and, as such, MyVax® can be made only for patients involved in clinical trials. However, if this therapy is approved, it will be possible to produce MyVax® for the vast majority of patients. In a small number of cases, it may not be possible to produce a personalized immunotherapy for a specific patient due to the biology of his/her tumor (i.e., the tumor may not express an idiotype (Id) protein or may not produce enough of the Id protein).

What to Expect When Receiving MyVax® Personalized Immunotherapy

Why is it recommended that patients have chemotherapy before receiving MyVax® Personalized Immunotherapy?

Experts believe that lowering the amount of tumor in the body through chemotherapy before giving MyVax® Personalized Immunotherapy may optimize the effects of the personalized immunotherapy, giving it the best possible chance to work.

How is MyVax® Personalized Immunotherapy given?

Each MyVax® Personalized Immunotherapy injection is given just under the skin, or subcutaneously, via a small needle. Each MyVax® injection is followed by a 4-day series of GM-CSF injections.

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What side effects do patients experience with MyVax® Personalized Immunotherapy?

Side effects that patients should expect to experience with MyVax® Personalized Immunotherapy include injection-site reactions, such as redness, swelling, bruising, itching, soreness, and/or some

include injection-site reactions, such as redness, swelling, bruising, itching, soreness, and/or some pain at the site of the injection. Some patients also experience flu-like symptoms, including fever, chills, nausea, and muscle soreness. These side effects may be related to the Id-KLH immunotherapy and generally occur in the few days after the injection, although they can last longer.

Side effects seen with the adjuvant, GM-CSF, include fever, bone or joint pain, flu-like symptoms (nausea, headache, tiredness), and mild skin reactions at the injection site. More information about GM-CSF side effects can be found at www.leukine.com.

As with any medication, there is a possibility of allergic reactions with MyVax®. Allergic reactions have been seen only in a small number of patients, and patients are monitored closely after each injection for signs of such a reaction. There are very effective medications available should they be required to counteract allergic reactions.

What can be done to manage these side effects?

Patients should discuss any side effects they are experiencing with their doctor, who will be able to recommend treatment options. Ice or heat may be applied to the injection site to minimize discomfort. Over-the-counter medications such as acetaminophen, aspirin, antihistamines, and ibuprofen can be useful in helping to combat flu-like symptoms and injection-site reactions. Use of these medications is permitted in clinical trials. Use of oral, inhaled, and/or topical corticosteroids or other medications that suppress the immune system are not permitted in clinical trials, as they may interfere with the immune response. If you are a patient in a Genitope clinical trial and you are unsure about a medication, consult with your healthcare team.

For suggestions on how to manage side effects associated with GM-CSF, visit www.leukine.com.

Talking to Your Healthcare Team About MyVax® Personalized Immunotherapy

I want to talk to my doctor about the possibility of receiving MyVax® Personalized Immunotherapy. What should I say?

Currently, the only way for patients to receive MyVax® Personalized Immunotherapy is to be enrolled in a clinical trial. Ask your doctor if any of the trials now enrolling patients are right for you. To learn more about MyVax® clinical trials, click here.

If MyVax® is approved, it will be important to talk with your doctor early about the possibility of incorporating MyVax® into your treatment strategy. This is partially because if MyVax® is a consideration, any biopsies can be performed with this in mind, and, if appropriate, tissue can be saved for the production of personalized immunotherapy. Also, knowing MyVax® is an option will help you and your doctor best plan the sequencing of treatments that may be needed.

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